



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Federal Express

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Warning Letter



Mr. Ming Shan Zhang, General Manager
Jiangyan Medical Products Factory
Baoqu, Jiangyan
Taizhou, Jiangsu, P.R. China 225521

Dear Mr. Zhang:

During an inspection of your firm located in Baoqu, Jiangyan Taizhou, Jiangsu, P.R. China, on March 10-12, 1997, our Investigator determined that your firm manufactures gauze sponges. These are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated under section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820 as listed below.

1. Failure of the quality assurance program to assure that all quality assurance checks are appropriate and adequate for their purpose, as required by 21 CFR 820.20(a)(4). For example:
 - a. There is no microbial testing of the finished gauze sponge devices to determine the presence and identity of any bacteria, molds, and yeasts. (This item was not listed on the FDA-483; however, it was discussed in the investigator's report.)
 - b. There is no testing of the water, used in the manufacturing processes of gauze sponge devices, to ensure the water quality is adequate for the operations performed.
2. Failure to have written quality audit procedures, and failure to conduct planned and periodic audits of the quality assurance program, as required by 21 CFR 820.20(b). For example, there are no written procedures for conducting internal quality audits of the quality assurance program, and no such audits are conducted.

3. Failure to control environmental conditions to prevent contamination of the device, and to provide proper conditions for each of the operations performed, as required by 21 CFR 820.46. For example:
 - a. There is a buildup of grime on the top section of the six tile covered storage bins and along the interior upper wall of some of the bins in which gauze products are allowed to dry during manufacturing.
 - b. There is a buildup of dirt and dust particles (particulate matter) on the floors, walls, ceilings, and wooden platform in the room storing incoming gauze material and in the manufacturing area.
4. Failure to have written cleaning procedures and schedules to meet manufacturing process specifications, as required by 21 CFR 820.56. For example, there are no written cleaning procedures, schedules for cleaning, or records of cleaning for six tile covered storage bins in which gauze products are allowed to dry during manufacturing. (This item was not listed on the FDA-483; however, it was discussed in the investigator's report.)
5. Failure to provide adequate washing and toilet facilities for personnel sanitation, as required by 21 CFR 820.56(a). For example, the toilet facilities do not have soap, cleaning solutions, or drying mechanisms for hand-washing of production personnel.
6. Failure to have procedures designed to prevent contamination of equipment, components, or finished devices by cleaning and sanitizing substances, as required by 21 CFR 820.56(b). For example, at various stages in the manufacture of the gauze sponge devices, the product is [REDACTED] however, there is no testing of the [REDACTED] to ensure its quality is adequate for the operations performed.
7. Failure to have buildings in which manufacturing and holding operations are conducted, be of suitable design and contain sufficient space to facilitate adequate cleaning and other operations, as required by 21 CFR 820.40. For example, product is stored on the floor at various stages of production, and an above ground "bridge" that connects the storage building to the manufacturing plant is not fully enclosed.

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8. Failure of personnel in contact with a device or its environment to be clean and suitably attired where lack of cleanliness, or suitable attire could adversely affect the device, as required by 21 CFR 820.25(b). For example:
 - a. Hair restraints do not completely cover hair, and some employees were observed not to be using hair restraints.
 - b. Employees handling gauze sponge devices do not routinely wash their hands during production, or before returning to their respective operations after a period of absence. Employees leaving the toilet facilities were observed washing their hands with water only and drying them on their laboratory coats.
 - c. Employees handling gauze sponge devices do not wear gloves during production.
9. Failure to retain all required records pertaining to the device for a period of time equivalent to the design and expected life of the device, but in no case less than two years from the date of release for commercial distribution, as required by 21 CFR 820.180(b). For example, device history records for gauze sponge devices are not retained for two years.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and the FDA-483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Other Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pending applications for premarket approval (PMA's) will be approved for products manufactured at the facility in which the above GMP violations were found until the violations have been corrected.

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Given the serious nature of these violations of the Act, all devices manufactured by Jiangyan Medical Products Factory, Baoqu, Jiangyan, Taizhou, Jiangsu, P.R. China, may be detained without physical examination upon entry into the United States until these violations are corrected.

In order to remove the devices from detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review. After we notify you that your response is adequate, it will be your responsibility to schedule another FDA inspection of your facility. As soon as the inspection has taken place, the implementation of your corrections have been verified, and you are notified that your corrections are adequate, your products may resume entry into this country.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. If the documentation is not in English, please provide a translation to facilitate our review. Your response should be sent to:

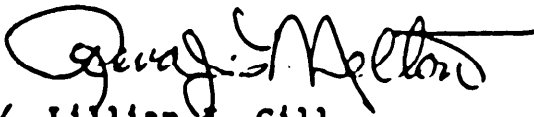
Mr. George Kroehling, Chief
General Surgery Devices Branch, HFZ-323
Office of Compliance
Division of Enforcement I
Center for Devices and Radiological Health
U.S. Food and Drug Administration
2098 Gaither Road
Rockville, MD 20850 U.S.A.

You may obtain general information about FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 800-638-2041 or through the Internet at <http://www.fda.gov>.

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If you have more specific questions about the contents of this letter, please feel free to contact Mr. Joseph L. Salyer at the above address or at (301)-594-4595, Ext.175 or FAX (301)-594-4636.

Sincerely yours,

for 
Lillian S. Gill,
Director
Office of Compliance
Center for Devices and
Radiological Health

CC: Mr. Pu Zhang, General Manager
China Meheco Yangzhou Import and Export
58, Ximeng Street
Yangzhou, Jiangsu, P.R. China 225002

[REDACTED]

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